

REMARKS

Upon entry of this paper, claims 1, 25, 26, 27, 44, and 53 have been amended, no claims have been cancelled, and no claims have been added as new claims. Thus, claims 1-27 and 44-53 are presently pending in this application. No new matter has been added.

Applicants gratefully thank the examiner for the indication of allowability of claims 45-49. In addition, applicants respectfully submit that all claims pending in the present application are allowable as described herein.

Applicants further thank the examiner for the indication of allowability of claim 3 if rewritten in independent form to include all the limitations of the base claim and any intervening claims. However, Applicants request further clarification concerning the statement of allowability of claim 3 as noted below, as it pertains to the allowability of claim 53.

Claim Objections

Claim 3 was objected to as being dependent upon a rejected base claim. Applicants previously presented new claim 53, which incorporated the characteristics of claim 3 into the characteristics of claim 1, in strict compliance with the Examiner's suggestions. However, the Examiner has rejected claim 53.

Applicants believe claim 53 is also allowable because it follows the Examiner's suggestion for modification of claim 3. If the Examiner requires further amendment to claim 53 for it to comply with the Examiner's suggestion, Applicants request that the Examiner contact Applicants' below signed representative.

In addition, Applicants consider claim 3 to be allowable, based on the remarks provided herein concerning the allowability of base claim 1.

Claim Rejections Under 35 U.S.C. §102

Claims 1, 2, 4-20, 24-27, 44, and 50-52 were rejected under 35 U.S.C. §102(e) as being anticipated by US Patent Number 5,269,755 to Bodicky, et al. (Bodicky '755). This anticipatory rejection is respectfully traversed in view of the following remarks.

Applicants strenuously request that the Examiner re-visit the Bodicky '755 reference in its entirety to appreciate that there is no disclosure in Bodicky '755 of an ePTFE sheath that radially stretches from an expanded diameter to an even greater diameter with the addition of fluid pressure. Furthermore, that even if this action were disclosed in Bodicky '755, such a teaching fails to anticipate the pending claims, which describe a collapsed configuration expanding to an expanded configuration.

The Assertion That Fluid Pressure Applied To The Device In Bodicky '755 Results In An Increase In The Radial Direction Is Wholly Unsupported

In the most recent Office Action, in the Response to Arguments, it states, "Examiner asserts that since the sheath is made of ePTFE material, given sufficient fluid pressure, the sheath (40) also stretches in the radial direction (see column 5, lines 26-27 and lines 32-34)." Applicants respectfully submit that this position is wholly unsupported by Bodicky '755, by the pending application, and by the material properties of ePTFE.

The Office Action provides two sections of Bodicky '755 to support the assertion stated above. Lines 26-27 of Bodicky '755 state, "Pores E are formed between the interconnected nodes C and fibrils D. The size of the pores E is a function of whether fibrils D are stretched, relaxed or compressed between nodes C which is in turn a function of whether ePTFE sheath 40 is stretched or compressed. (underlined portion is specific to lines 26 and 27)" Lines 32-34 of Bodicky '755 state, "The chosen pore size of the pores E of the ePTFE material is a function of the viscosity of the medicament or other liquid as well as the injection pressure, if any, applied to the medicament or other liquid. (underlined portion is specific to lines 32-34)"

However, this language does not support the assertion that, “given sufficient fluid pressure, the sheath (40) also stretches in the radial direction.” Applicants submit that the language specifically states the sheath can stretch or compress to adjust the pore size of the material. ***The stretching and compressing has no substantial effect on the diameter of the sheath.*** Again, Applicants respectfully, but strenuously, request that the Examiner review the technical content of the disclosure in Bodicky ‘755, and the material properties of ePTFE. The cited language, and Bodicky ‘755 in general, is describing a characteristic of ePTFE whereby *longitudinal stretching* of the material pulls fibrils taut, thereby increasing pore size, and *longitudinal compression* of the material creates “bent or wavy” fibrils (*see* Bodicky ‘755, col. 5, line 10) which decreases pore size. This description pertains to longitudinal stretching and compressing. ***This does not equate to expanding the diameter (radial) dimension of a tube or balloon formed of ePTFE.***

The diameter of the ePTFE tube is measured along a direction (i.e., the latitudinal direction) of the ePTFE material that is perpendicular to the longitudinal dimension being stretched and compressed in Bodicky ‘755. *In the latitudinal direction (as applied in this discussion), ePTFE is inelastic*, as understood by one of ordinary skill in the art, and stated in Applicants’ description (“The method includes the step of forming a tube of inelastic, fluoropolymer material” *see* Description, page 3). After the various processing steps performed to create the radially expandable device are completed as described, the ePTFE material is inelastic in the latitudinal/radial direction. The structure of nodes and fibrils creates a unique material that when formed into a tube or cylindrical type structure, ***will not stretch or change dimension in a perceptible manner in the radial/latitudinal/diametric dimension.***

Said differently, if one takes a graft of ePTFE formed into the shape of a tube (where the latitudinal direction of the ePTFE is in the direction of the diameter of the tube), and one pulls on either end of the tube, the ePTFE stretches in the lengthwise/longitudinal direction (extending the length of the tube) but the diameter of the tube (the latitudinal/radial dimension) remains substantially unchanged.

Viewed in a different context, a square piece of ePTFE having a standard coordinate axis applied thereto (x-direction being left to right and y-direction being up and down), will have

different properties with regard to elasticity and stretching in the x-direction verses the y-direction. Assuming the nodes are aligned parallel to the y-direction, and the fibrils extend generally along the x-direction, the square of ePTFE material will stretch and compress along the x axis in the x-direction (bending and pulling the fibrils taut). However, the square of ePTFE material will be substantially inelastic and not perceptibly stretch or compress along the y axis in the y-direction. As described in Bodicky '755, compression and stretching in the x-direction will close and open pores (bending and pulling the fibrils taut), respectively. However, attempts to stretch or compress in the y-direction will have no substantial effect. The longitudinal direction in Bodicky '755 equates to the x-direction and the radial/latitudinal/diameter direction equates to the y-direction in this example. Thus, there is no substantial change in the diameter if pressure or force is applied to attempt to expand the sheath in the y-direction of the ePTFE material.

Accordingly, the disclosure of Bodicky '755 does not teach that the ePTFE is "deployable from a collapsed configuration to an expanded configuration." *See* amended claim 1. Nor does this language support the Examiner's assertion that "given sufficient fluid pressure, the sheath (40) also stretches".

The "Pressure" Described In Bodicky '755 Does Not Expand The Diameter Of The Sheath

The reference to the introduction of fluid pressure in Bodicky '755 has nothing to do with stretching the diameter of the sheath. Instead, the "injection pressure" is mentioned as one factor in determining what size to make the pores to result in the desired amount of liquid (having a certain viscosity) passing through the sheath.

The lines cited in the Office Action, as well as the Bodicky '755 reference in general, fail to disclose the use of fluid to expand the sheath "from a collapsed configuration to an expanded configuration." *See* amended claim 1. Applicants are requesting that the independent claims be amended to more clearly distinguish that the radially expandable device of the present invention starts in a collapsed configuration (as shown in **FIG. 1**) and upon the application of fluid pressure, expands to an expanded configuration (as shown in **FIG. 2**). Applicants would again like to stress that the radially expandable device of the present invention does not undergo

substantial or perceptible stretching or expansion in the radial direction of the diameter of the radially expandable device once the device is expanded. Instead, the radial expansion described and claimed refers to the initial configuration of a collapsed structure expanding to an expanded structure. This is a difference that is not disclosed, taught, or suggested in Bodicky '755.

In fact, Bodicky '755 specifically teaches away from a device having a collapsed diameter position that is subsequently radially expanded. Bodicky '755 states, "seal 44 retains a nearly constant diameter for sheath 40 at its proximal end despite any pressure applied to the outer surface of the ePTFE sheath 40 by the patient's urethra." *see* column 6, line 67 to column 7, line 2. Applicants again submit, Bodicky '755 does not teach that the ePTFE is "deployable from a collapsed configuration to an expanded configuration." *See* amended claim 1. In fact, Bodicky '755 ***specifically states that the diameter of the sheath is held constant. An attempt to collapse the sheath in Bodicky '755 is specifically prevented by the seal.***

As such, Applicants respectfully submit that Bodicky '755 fails to anticipate the pending claims. Applicants request reconsideration and withdrawal of this rejection.

Claim Rejections under 35 U.S.C. §103

Claims 21-23 and 51-52 were rejected under 35 U.S.C. §103 as allegedly being unpatentable over Bodicky '755. This rejection is respectfully traversed in view of the following comments.

In view of the above remarks, Bodicky '755 fails to teach or suggest all elements of the pending claim 1, from which claims 21-23 depend. Claims 51-52 likewise depend from a claim (claim 50) that includes the same element in claim 1 of having a member deployable from a collapsed configuration to an expanded configuration (as amended). As such, Bodicky '755 fails to teach or suggest all elements of claim 50.

Applicants respectfully submit that unless a *prima facie* case of unpatentability with respect to known facts is established, applicants are not obliged to proffer any evidence of

nonobviousness. To establish a *prima facie* case there must be some suggestion or motivation, either in the prior art or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine multiple reference teachings. There must then be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claimed limitations.

Again, Applicants respectfully submit that the sheath 40 is not a radially expandable device as evidenced by the figures of Bodicky '755 and the detailed description. The noted figures show the Foley catheter with the balloon portion on the end of the catheter inflated. However, there is no indication in the figures of the sheath 40 experiencing any change in radial dimension. In fact, specific language as cited from columns 6 and 7 indicate that the seal prevents the sheath from existing in a collapsed configuration. The sheath cannot collapse, and due to the material properties of ePTFE, the sheath cannot substantially expand beyond the inflated state (when fluid pressure is provided) to stretch the diameter of the sheath. Thus, the sheath of Bodicky '755 is not a "radially expandable device."

Applicants, therefore, respectfully submit that the pending claims are non-obvious with respect to Bodicky '755. Reconsideration and withdrawal of this rejection are accordingly requested.

Amended Claim Language

Applicants respectfully submit that the amendment made to the independent claims 1, 25, 26, 27, 44, and 53 does not rise to the level that would require an additional search by the Examiner. The language merely clarifies that which Applicants originally described in the detailed description, and have been additionally stating in repeated Responses. Specifically, the Examiner has already searched on a radially expandable fluid delivery device that is "deployable from a first, ~~reduced diameter~~collapsed configuration to an ~~second, increased diameter~~expanded configuration." The modification of language from first and second diameters, to collapsed and expanded is merely a different way of stating the same action that has been thoroughly described and remarked upon by Applicants during the course of this prosecution. Accordingly, no new matter has been provided, and no new search is required.

CONCLUSION

In view of the foregoing, it is respectfully submitted that this application is now in condition for allowance. Applicants courteously solicit allowance of the claims in the form of a Notice of Allowance. Should there be any outstanding issues of patentability following the entry of this response, a telephone interview is respectfully requested to resolve such issues.

Please charge any shortage or credit any overpayment of fees to our Deposit Account No. 12-0080. In the event that a petition for an extension of time is required to be submitted herewith, and the requisite petition does not accompany this response, the undersigned hereby petitions under 37 C.F.R. §1.136(a) for an extension of time for as many months as are required to render this submission timely. Any fee due is authorized to be charged to the aforementioned Deposit Account. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

LAHIVE & COCKFIELD, LLP



By: Sean D. Detweiler
Reg. No. 42,482
Attorney for Applicants

28 State Street
Boston, MA 02109-1784
Tel: (617) 227-7400
Fax: (617) 742-4214

Date: May 11, 2004